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09/295,691	04/21/1999	JON FAIZ KAYYEM	A-67465/RFT/	7483

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FLEHR HOHBACH TEST ALBRITTON &  
HERBERT L L P  
SUITE 3400  
FOUR EMBARCADERO CENTER  
SAN FRANCISCO, CA 941114187

EXAMINER

STARSIK, JOHN S

ART UNIT

PAPER NUMBER

1743

DATE MAILED: 01/13/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
09/295,691

Applicant(s)  
Jon Faiz Kayyem

Examiner  
J. STARSIAK

Group Art Unit  
1743

— The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address —

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- ☒ Responsive to communication(s) filed on 30 October 2002
- ☒ This action is FINAL.

- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- ☒ Claim(s) 36-39, 45-47, 49, 50, 51, and 52 is/are pending in the application.
- ☐ Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 36-39, 45-47, 49, 50, 51, and 52 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement

## Application Papers

- ☒ The proposed drawing correction, filed on 10/30/02 is ☒ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119 (a)-(d).
- ☐ All ☐ Some\* ☐ None of the:
  - ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_
  - ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a))

\*Certified copies not received: \_\_\_\_\_

## Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other \_\_\_\_\_

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## **DETAILED ACTION**

### ***Drawings***

The proposed drawing correction and/or the proposed substitute sheets of drawings, filed on 30 October 2002 have been approved. A proper drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The correction to the drawings will no

### ***Claim Rejections - 35 USC § 112***

Claims 36-39, 45-47, 49, 50, 52, and 53 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Despite the length of the specification (113 pages) the portion of the specification directed to the structure of the device (a device is being claimed). Instead the bulk of the specification is directed to long lists of possible options for the "self-assembled monolayer" and "ligands". Also there is a long lists of possible processes performed in the sample handling module and the reaction module. Moreover, the only portion of the specification directed the structural organization of the possible elements of the invention is the brief description of the drawings. The remainder of the

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specification is directed to specific examples for each of the elements, individually. Moreover, some elements are not even described. For example, it is obvious that the "detector electrode" requires a counter- electrode. Yet, the specification is devoid of any discussion of a counter electrode. [Similarly in order to inject fluid containing the sample into the device fluid from somewhere in the device must exit. The specification provides no structure for this.]

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 36-39, 45-49, 50, 52, and 53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 36-39, 45-47, 49, 50, 52, and 53 are rejected as incomplete. Specifically, the combination of elements recited as "a detection module" cannot perform the detection function. From pages 98-110 of the specification it appears that all embodiments of the detector module require elements in addition to those recited in claim 36. The additional elements depend of the technique used. For example if fluorescence detection is used a light source and a photodetector are required. Also, a counter electrode is required. Claim 50 recites, "A device according to claim 48". Claim 48 has been canceled. Claim 52 recites, "further comprising an valve". This claim fails to recite any structural relationship between said valve and the elements recited in claim 36.

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***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claim 36 is rejected under 35 U.S.C. 102(e) as being anticipated by Segal et al..

Segal et al. teaches [col. 8, lines 47-53]: "In one embodiment, the diagnostic card device of the present invention includes the following elements which will be further described herein below: a support substrate, which includes a sample introduction region, a biosensor, a sample flow pathway communication with said sample-introduction region and said biosensor...". See Figures 8A and 16. Segal et al. teaches [col. 11, lines 36-53]: "The devices can include, in conjunction with the sample-introduction region, means for sample pre-treatment, such as filters for red blood cells....The device can include a separation device for filtering the sample....Sample

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pretreatment can also .... reduce or remove interfering substances such as immunochemical cross-reactants, redox substances and the like.”. The detector elements recited on several embodiments of the biosensors of Segal et al., particularly the embodiment illustrated in figure 13 and described from col. 15, line 18 to col. 16, line 38.

### ***Response to Arguments***

Applicant's arguments filed 21 March 2002 have been fully considered but they are not persuasive.

Applicant's arguments that the examiner's rejection of the claims 36-53 under 35 USC 112, first paragraph, are not well-taken. The applicant alleges that all the subject matter that the examiner states is lacking in the present specification is known in the prior art. However, the applicant fails to positively demonstrate that any of said subject matter is known in the art. Regarding applicant's argument directed to a "counter-electrode". While the specification of does contain two recitations of a counter-electrode. The specification fails to recite any structural details of said counter- electrode or the spatial relationships between said counter-electrode and the other elements of the invention. The applicant has no arguments directed to the need for an "exit".The applicant fails to directly address the issue of the incompleteness of the detection module recite in the claims. In other words the applicant fails to demonstrate how a detection module with only the elements recited in the claim can perform the detecting function.

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Applicant's declaration fails to overcome the rejection based on Segal for the following reasons. First, the exhibit I is merely a short list of handwritten notes (some parts of which are unreadable). In other words, the exhibit fails to demonstrate that the applicant had in his possession prior to 02 March 1999 the detail device recited in claim 36. Second, the applicant fails to demonstrate that the "CMS technology" in the notes corresponds to the present invention.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to John S. Starsiak Jr. whose telephone number is (703) 308-1797. The examiner can normally be reached on Monday to Wednesday from 8:00 AM to 3:30 PM and on Thursday and Friday from 8:00 AM to 12:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on (703) 308-4037. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9310.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

  
John S. Starsiak Jr.

10 January 2003

  
Jill Warden  
Supervisory Patent Examiner  
Technology Center 1700